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The Honorable Roy Schmidt
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Representative Schmidt:

This letter is our response to the proposed bill, H.R. 4583, that would amend section 5133 of the Public Health Code regarding HIV testing. **The Michigan Infectious Diseases Society (MIDS)** is made up of 150 physicians and includes many of the physicians who perform HIV clinical care and research in the State of Michigan.

At present in the State of Michigan, a written informed consent is required from patients for testing except in situations where healthcare workers have a significant occupational exposure to bodily fluids with unknown HIV status. The circumstances that led to this consent process included strong societal discrimination, limited access to care and few treatment options for those diagnosed with HIV infection. Because of extraordinary advances in the treatment of HIV and extensive federal and state funding for counseling and treatment, the life expectancy of HIV infected persons approaches that of uninfected individuals. The widespread use of HIV treatment has reduced deaths due to AIDS. From a public health standpoint, there is also increasing evidence of reduced rates of new infections among contacts of those on HIV treatment. In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) enables public health authorities to protect sensitive patient health information that may lead to discrimination. As a result, members of our society agree with the timing of legislation that may potentially increase the appropriate use of HIV testing to identify more of the estimated 25% of HIV infected individuals in our state who are not aware of their infection. The very knowledge of one's HIV status has been shown to lead to reduced rates of transmission. **Moreover, it is estimated that over 50% of new sexually transmitted HIV infections occur from HIV infected individuals who are unaware of their HIV status.**

The Centers for Disease Control (CDC) recommended in 2006 that all patients in all health care settings be offered opt-out HIV testing without separate written consent and prevention counseling. At present, Michigan is one of only nine states that requires written consent and one of ten states that require post-test counseling (Annals of Internal Medicine, 2009:150: 263-9). Thirty-one states have no requirement for consent, allow opt-out testing or include HIV testing with the consent for medical

care provided by healthcare providers. In addition, the Detroit metropolitan area is among the top 15 cities nationally in terms of HIV infected individuals (CDC). Thus, MIDS strongly urges adoption of a more proactive approach to patient consent is needed.

The current version of H.R. 4583 that is being proposed requires "information appropriate to the test subject both before and after the test is administered". In addition, performing the test requires "informed consent of the test subject ... which means written or verbal consent to the test by the test subject or the legally authorized representative of the test subject". In addition, "the physician or health facility shall document the provision of informed consent, including pretest information, and whether the test subject or the legally authorized representative of the test subject declined the offer of HIV testing. Informed consent for HIV testing shall be maintained in the patient's medical records."

It is the belief of our society that this proposed bill does not sufficiently move Michigan into compliance with the recommendations for testing provided by the CDC. The series of steps that would be required (provide pre-test information, obtain consent, document consent and perform test) are difficult to perform in a timely fashion in healthcare settings where testing is most needed (emergency departments, sexually transmitted diseases clinics). **We believe that ideally consent for HIV testing should be included along with the consent for medical care that is provided at all healthcare facilities.** This in fact is addressed on page 5 of the proposed bill (lines 7-15) and it states that "nothing in this section prohibits a physician or health facility from combining a form used to obtain informed consent for HIV testing with forms used to obtain consent for general medical care ... if the forms make clear that the subject may consent to general medical care ... without being required to consent to HIV testing".

We agree with including HIV testing in the consent for medical care with the ability to opt-out provided on the same form (except when there has been an occupational exposure to a healthcare worker). This will reduce obstacles to healthcare providers by eliminating the need for additional pre-test counseling, obtaining and documenting informed consent. In addition, we agree on the section of the bill that states that all individuals with positive tests be given this information and appropriate counseling (pages 7-8, starting with line 24). **Furthermore, it is at this point where information provided by the Department of Community Health should be given to patients to provide information on HIV infection, methods of transmission, treatment and how to find a provider.**

By reducing the burden provided on healthcare providers to provide HIV testing as recommended by the CDC, we hope to increase patient knowledge of their HIV status. This will allow earlier treatment, thus providing improved healthcare outcomes for the patient and decreased transmission to others. We hope you will strongly consider our proposed changes prior to submitting the proposed bill to the House of Representatives. In addition, we welcome further dialogue with your office as the final version of the bill is prepared.

To all:

The HIV consent bill was passed on 3/24/10 by the HR without any of our suggested changes. Please note that physicians were only notified of this bill on 3/9/10 by the MDCH after it was introduced to the HR and we provided a response by 3/19/09 (letter attached). The following link is the summary of the bill, provided by the House Legislative Analysis Section. The bill as written essentially is inconsistent about the method of consent and in its strictest interpretation, changes nothing from our current system.

<http://www.legislature.mi.gov/documents/2009-2010/billanalysis/House/pdf/2009-HLA-4583-3.pdf>

The following is a list of those who supported the bill (from the above link):

POSITIONS:

A representative of **Spectrum Health** testified in support of the bill. (3-9-10)
A representative of **ACLU of Michigan** testified in support of the committee substitute. (3-9-10)
A representative of the **Triangle Foundation** testified in support of the committee substitute with changes. (3-9-10)
Medical State Medical Society (MSMS) indicated support for the bill. (3-9-10)
Michigan Association of Health Plans indicated support for the bill. (3-9-10)
Beaumont Hospitals indicated support for the bill. (3-9-10)
Michigan Chapter - American Academy of Pediatrics indicated support for the bill. (3-9-10)
Michigan Health & Hospital Association indicated support for the bill. (3-9-10)
Department of Community Health indicated support for the concept of the bill. (3-9-10).

The most notable omissions are Michigan Infectious Diseases Society (MIDS) and representatives of the three health systems which provide the highest volume of HIV care in Michigan! I am copying several other individuals on this Email to summarize MIDS stance on the bill (see attached letter from last Friday, sent prior to the bill going for vote) and to hopefully get some information on whom else actually supported the bill e.g. from Spectrum Health, MDCH, MSMS, Beaumont Hospitals, Michigan Chapter of American Academy of Pediatrics (I have already talked to ACLU on this).

To summarize how the bill does not increase the likelihood of achieving increased ease of testing, please see the excerpts from analysis of the bill (from the above link):

1. Rationale of bill

"If physicians could order HIV testing in a manner more akin to that for other medical tests, more patients may agree to the testing." YET "Because of the serious nature of HIV infection, and the impact that a positive test result can have on an individual, it is important to provide more information and consent to HIV testing than what is necessary or appropriate to consent to a routine blood panel."

2. Method of consent

Thus, the bill would accomplish the objective by replacing the current requirement of providing counseling and information and obtaining a signed consent form with the requirement to provide certain information and obtain either written or verbal consent. Some additional information would be added to that provided to test subjects."

"In addition, the bill would add a requirement that the physician or health facility document the provision of informed consent, including pretest information, and whether or not the test subject or his or her legally authorized representative declined the offer of HIV testing. The informed consent for HIV testing would have to be maintained in the patient's medical file.

3. Pretest information

"Currently, the Department of Community Health is required to **develop a pamphlet regarding HIV testing** that must be given to a test subject by the physician ordering the HIV test. The **pamphlet must contain a model consent form that contains certain information** as prescribed in statute. The bill would instead require information substantially similar to what is currently contained in the pamphlet to be provided to test subjects, though some revisions would be made."

4. Inconsistency within the bill

"**Nothing in the bill would prohibit a physician or a health facility from combining a form used to obtain informed consent for HIV testing with forms used to obtain consent for general medical care** or any other medical tests or procedures if the forms made clear that the subject could consent to general medical care, tests, or medical procedures without being required to consent to HIV testing and, if applicable, that the subject could decline HIV testing at any time before the administration of the test."

At this point, the bill will proceed to the State Senate for a vote. If it is passed in its current version, it is unlikely that this issue will be brought up again anytime soon due to other legislative priorities (last time bill was approved was 1988!). All of the members of the MIDS executive council and the President feel that this bill is deficient in improving our ability to identify and treat people infected with HIV and help prevent the spread of this disease. I have attached a file from the MDCH webpage detailing the continued rise of HIV in our African-American youths in Michigan (<http://www.michigan.gov/mdch/0,1607,7-132--227030--,00.html>).

It is time to take definitive action in preventing and treating HIV. By maintaining the status quo of performing testing to identify infected patients (as the points above clearly point out) and creating legislation that confuses providers (instead of providing guidance!). The continued requirement for Informed Consent and Pre-test counseling are in conflict with the CDC's recommendation for testing and Michigan will remain behind most of the rest of the country in our approach to HIV testing (see:

<http://www.annals.org/content/150/4/263.full.pdf+html>).

My final vignette is from my most recent attempt to initiate rapid HIV testing in our hospital's emergency department (a 75,000 visit/year site in the epicenter of Michigan's HIV epidemic). As CDC funding for this type of project has dried up considerably, I was informed that while no funds could be provided for those who would do pre- and post-test counseling, I could receive the use of test kits through the MDCH

on a pilot basis. After explaining to an Emergency Department colleague that there is a lack of funds for those to provide counseling and the likely new law for HIV testing in Michigan won't change any of the time restraints involved in the process, he simply shook his head with bewilderment when asked about implementing the process in our Emergency Department. As someone who has provided HIV care in Detroit for the last 12 years, the current law and recently passed HR bill also makes me shake my head in wonder.

Sincerely,

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